510(K) Summary

K093327

MAY 10 2010

Date:	**10/22/2009**	
Submitted on behalf of:		Michael Zhu Shanghai Intco Electrode Manufacturing Co., Ltd. No. 1299, Hubin Rd, Fengxian District Shanghai China Tel: ++ 0086-21-57451159 Fax: ++ 0086-21-57451877
Submitted by:		Lead-Lok, Inc. 814 Airport Way Sandpoint, ID 83864
Contact person:	Chris Healy, President	Tel: 208-263-5071 Fax 208-263-9654
	Trade Name:	INTCO Tab Electrode
	Common Name:	Disposable ECG Electrode
	Classification Name	Electrode, Electrocardiograph
	Product Paned	Cardiovascular
	Product Code	DRX
	Product Class	Class II Device
	Regulatory Reference:	CFR 870.2360
Predicate Device		Leonard Lang GmbH Skintact ECG Tab Electrode K030509
Description:		INTCO Tab electrodes are composed of PET tape, Ag/AgCl or carbon conductive layer, and a conductive gel. These are configured as ten electrodes applied to a siliconized card, with 10 cards per pouch
Intended Use:		INTCO Tab Electrodes are designed for use with general electrocardiographic procedures when ECG monitoring is deemed necessary by a physician. Such procedures include ECG surveillance and diagnosis recording. INTCO Tab Electrodes are non-sterile and are to only be used on intact (uninjured) skin.
Substantial Equivalence:		INTCO Tab Electrodes with solid adhesive gel are substantially equivalent to Skintact ECG Tab Electrodes (K030509). Physical and technical characteristics, including materials used, intended use, and conformance to standards are comparable.
Performance Summary:		INTCO Tab Electrodes have been tested and conform to recognized consensus standard 3-52: ANSI/AAMI EC12:2000/(R)2005
Biocompatibility:		The biological safety of the INTCO Tab electrodes has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The conductive gel has been tested on the basis of ISO 10993-1 and found to be non-irritating, non-cytotoxic, and non sensitizing.
Shelf life:		Accelerated aging tests were performed to substantiate an expiration of 24 months.
Conclusion:		INTO Tab Electrodes are substantially equivalent to the predicate device approved as K020003 and do not introduce new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 10 2010

Shanghai Intco Electrode Manufacturing Co., Ltd
c/o Mr. Chris Healy
Lead-Lok, Inc.
814 Airport Way
Sandpoint, ID 83864

Re: K093327
Trade/Device Name: Intco Tab Electrode
Regulatory Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrode
Regulatory Class: II (two)
Product Code: 74 DRX
Dated: April 23, 2010
Received: April 27, 2010

Dear Mr. Healy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

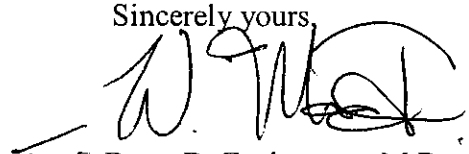
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093327

Device Name: INTCO Tab Electrode

Indications for Use:

INTCO Tab Electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include patient ECG surveillance and ECG diagnosis recording. INTCO Tab Electrodes are non-sterile and are to be used on intact (uninjured) skin.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093327